# FINAL REPORT: "WORKSHOP ON INNOVATION AND REGULATION IN AGRICULTURE"

James B. Hunt, Jr. Library at North Carolina State University
July 28-29, 2016

## EXECUTIVE SUMMARY

The need for innovative technologies comes at a time when modern agriculture is subject to increasing pressure and scrutiny from a public that has grown distrustful of new technologies, even as it enjoys the benefits these innovations provide. Balancing public perception with the need to sustainability feed a growing world population is one of the key challenges of our time. Recognizing that this future food challenge must be addressed now, leaders from government and regulatory agencies, academia and industry came together in a two-day workshop to discuss ways in which they can work together to optimize the process of bringing critically-needed innovation to agriculture.

Through a series of plenary discussions and breakout workshops, the participants reviewed possible ways to facilitate greater understanding and acceptance of beneficial innovations and build a process for delivery of those innovations to market that help alleviate public concern. Challenges to implementing these improvements were summarized in the following general themes:

- Technology in the agricultural industry is entering a period of major change, bringing new opportunities to farmers and new challenges to regulatory authorities
- Transparency is critical to establish public trust and credibility as innovative products are introduced into the marketplace
- Effective education and communication are essential to improve innovation acceptance
- Multidiscipline collaborations are the key to support our regulatory process and help engender public trust

To adequately address these themes, an effective platform for enhanced interaction between academic, government, industry and regulatory sectors is needed to develop collaborative research efforts that facilitate a common understanding of the benefits of innovations and addressing potential issues in a more timely and predictable manner. Because such a platform is currently lacking, the participants fully endorsed the formation of a Steering Committee to help develop, recommend and pursue an improved process by which novel technologies can be developed, regulated and introduced within an efficient and appropriate framework.

In its final assessment, the workshop underscored the need for greater communication, education and collaboration, not only among the government, regulatory authorities, academia and industry, but also between each of these sectors and the general public. As one participant succinctly summarized, the task ahead is to "develop a long-term strategic plan to use regulatory sciences to affect positive change for social acceptance of new technologies in agriculture." Failure to implement a more comprehensive approach will almost certainly jeopardize future agricultural innovation, just when it is needed the most.

# Summary of Workshop Activities and Outcomes

## Welcome

Bob Graney (Bayer) and Steve Lommel (NCSU) opened the workshop by welcoming the attendees and thanking them for taking time out of their busy schedules to participate.

## Workshop Goal

Establish an effective platform for enhanced interaction between academic, government, industry and regulatory sectors to focus collaborative research efforts on facilitating greater understanding and acceptance of beneficial innovations by addressing potential issues in a timely and predictable manner.

## Expected Outcomes

- An improved understanding of how the science that each stakeholder conducts contributes to the safety determination, regulatory approval and public acceptance of new technologies
- Assessment of the strengths and weaknesses of the current scientific and regulatory process and identification of areas that need improvement through collaborative research
- Proposals for instituting improvements including assessing existing & required funding opportunities
- Establishment of a steering group to summarize and implement recommendations including prioritizing and selecting trial projects

Workshop attendees added their individual expectations, which centered on the following themes:

Partnerships – engage in better working relationships/collaboration between public and private entities regarding research needed to support technology development and implementation

Public Acceptance – build relationships with consumers and end-users to restore trust, perception and acceptance of scientific research and novel technologies

Communication – increase transparency to increase public understanding and demystify the science of risk assessment to gain broader support for agricultural innovation

Regulatory Science – prepare for evolving regulatory challenges (e.g. pollinators, endangered species) and improve education/training to increase competencies and improve public confidence

Funding – need to set priorities on key issues and fund appropriately, especially between university and private industry research, while ensuring that such research will not be perceived as "tainted"

## Synopsis of Plenary Session Speaker Presentations

### Iain Kelly – Bayer's Crop Science Division

Today's technologies provide greater agricultural benefits and fewer risks than ever before, but the public's perception is that risks are increasing, especially in the environment (water, pollinators, endangered species, and endocrine disruption in wildlife). With relatively few modes of action (MOA) available to farmers, maintaining current products or finding new crop solutions that will satisfy public opinion is becoming increasingly more difficult. The U.S. remains the most stable exporter of food, but cultural differences regarding regulation between North America and Europe can disrupt the flow of trade. Recent industry studies show that, on average, the cost of developing a new crop protection active ingredient is $286 million and it requires 11 years from discovery to commercialization. A new genetic trait costs $135 million and it requires 12-16 years to commercialize. High costs, coupled with a lack of regulatory predictability across the globe, are a critical problem for the agricultural industry, especially for research-based companies that depend on regulatory certainty to justify this investment.

### Sally Schneider – USDA-Agricultural Research Service (ARS)

The ARS manages 17 national programs and 800 research projects. Its mission-driven research focuses on technologies developed by ARS (or others) and risk assessments for their uses. Over the next 5-15 years, agriculture will become more integrated, site-specific, data-intensive and data-informed, from the microbiome level to the watershed. ARS will continue to focus on yield and how we can narrow the gap between potential yield and that currently achieved by farmers. Research areas of interest include gene-editing, microbiome, soil health, nutrient management, field-based phenotyping, waste to value-added, food safety and quality, and sustainability. By networking with others in creative partnerships, ARS hopes to assist farmer access to new innovations that can have a long-term impact on agriculture, especially since such technologies become more affordable over time. Challenges to overcome include issues over intellectual property, big data, open data, public perception, and resource availability.

### Steve Lommel – NC State University, College of Ag and Life Sciences

NCSU's new Plant Science Initiative (PSI) is designed to foster interactive collaboration among multi-disciplinary teams (including corporate and government partners) to solve the key issues facing agriculture. The PSI is already 90 percent funded and has approval to begin building construction. As we are in the development phase of the PSI, four task forces have been formed to create operational and planning structures (Governance, Research & Technology, Advocacy, and Workforce Development & Public Awareness). A guiding principle for the task forces is to create a structure that will use diverse teams operating for limited periods of time to deliver agricultural solutions to farmers. To achieve this, we need to create the next generation of science-based regulators using professional development and continuing education, including a regulatory science curriculum (already underway at NCSU). We should consider using the successful model of public, private partnership that was developed by IR-4 as we move forward, so that we can get ahead of the curve on new technologies and not be caught unaware, like we did with GMOs.

### Chip Morgan – Delta Council

The Delta Council is an area economic development organization representing all phases of the economy in the delta region of Mississippi (about 34,000 jobs – 12 percent of which are on the farm). Agriculture's prosperity is dependent on the successful interactions of the diverse organizations represented in this workshop. We require high standards on food safety, human health and the environment that are based on regulations and specifications the public accepts. Our industry also requires a predictable process for decision-making, which incorporates the views of many. We cannot preserve our natural resources and grow crops productively unless we remain focused

on science, without being unduly swayed by the voices of single-issue advocacy groups. We must strengthen the trust between our companies, agencies and regulators. When faced with an illegal use situation in farm raised catfish, the Council created a "Locker Room" where frank discussions among diverse interests could be discussed and a successful strategy for dealing with the problem could be implemented. We should consider using this concept on other regulatory issues.

### Rick Keigwin, U.S. EPA, Office of Pesticide Programs

The use of a "word cloud" shows that terms like innovation, creativity, development and idea are all perceived positively by the general public. By contrast, word clouds associated with biotechnology and pesticides are viewed negatively and we must address this reality. If we cannot find opinion leaders who can validate the safety of new technologies, then all of the great science conducted for innovation will do little to gain the public's confidence. We need to understand where the science is going to build the "safety side" of innovation, supported by "validators of safety" within the stakeholder community. We need transparency (not just a public notice) and a real dialogue about the science and benefits that is based on full public engagement.

| Challenges for EPA | Opportunities |
|---|---|
| What is needed to demonstrate safety?<br><br>What data are necessary to measure safety?<br><br>What expertise is needed from government? | Broader public private partnerships (PPP)<br><br>More intergovernmental collaboration<br><br>Greater public education |

### Follow-up questions for Rick Keigwin:

*What does transparency look like for EPA?*

We must show that the work has been done and properly evaluated. Although it's not a vote, we should bring the public into the discussion during the decision-making process to increase public acceptance.

*Transparency has improved in the past 20 years, but has it helped or just fueled the fire?*

As we've increased transparency, it has also added more time to the registration process. Litigation is much more common today and although this is not a result of transparency, it does potentially reveal a distrust of government.

*How does EPA conduct public education and training to eliminate bias?*

We constantly try to educate our staff about agriculture. About 25% of the office travels to experience agriculture during the year. We also bring in speakers and land grant researchers to talk to the staff.

*30 years ago, many people in OPP came from farms, but that is not the case today. Is this a problem?*

There also are many challenges involved in hiring at the federal level. At OPP we hire many returning Peace Corps volunteers, many of whom have agricultural experience.

## Speaker Panel Discussion – Questions from the Workshop Participants

Panelists: Sally Schneider, Steve Lommel, Iain Kelly, Chip Morgan, and Rick Keigwin

The following is a composite of the general audience questions and responses from the speakers following the presentations of Day 1:

### What can be done to improve the level of public understanding when it comes to innovation?

People are inclined to adopt technologies they find useful (e.g. cell phones/GPS), but have a harder time accepting those for which they see little value and perceived risks (for some that includes modern agricultural practices). Unfortunately, there is a general distrust of industry and government, which adds to the problem. Food is important and people see a straight line between nutritious food and a healthy life, but they don't see the line connecting crop protection products to better food. We need all agencies (FDA, EPA, and USDA) to speak the same language regarding science-based regulation.

### How does EPA weigh public opinion when the public has little knowledge of science-based regulation?

Public opinion is important, but the public often may be intimidated or lack confidence in new technologies. However, as a public agency, the EPA must consider the views of the general public. EPA strives to ensure the public has the best information they need to assess our decisions. It handles a lot of scientific information, but most of that doesn't get to the public, so the public often reacts to the worst-case scenario. We should learn from how the public has reacted in the past.

Trust is a huge factor in terms of public acceptance. The best science won't overcome a low level of trust. We need to find credible voices to help deliver highly technical regulatory information in a way the public can understand and trust. Since we need to frequently reassess previous regulatory decisions per FIFRA requirements, it makes it even harder to explain a product's "safety risk" to a suspicious public. It doesn't help that some agencies are sometimes in public conflict with each other.

Perhaps a good model to emulate would be the National Pollinator Strategy, which brought all of the agencies together to work out what was most needed to protect pollinators. This is similar to the "Locker Room" concept that Chip Morgan discussed earlier.

### What has more regulatory influence today – advocacy or science?

Most believe that science should be the predominant driver of regulatory decisions, but there is a great difference when comparing the U.S. to Europe (which is swayed more by public pressure). While science may be the primary driver here in the U.S., it seems that advocacy speaks louder, forcing the science to be "proven" over and over again. While FIFRA sets clear rules of engagement, the trend toward increased litigation is a dramatic change from 20 years ago.

### How does the USDA synthesize and prioritize grower needs?

USDA looks at a 5-year calendar in planning its needs and brings in customer stakeholders to solicit input. Budget restrictions make this data gathering more difficult, so the use of teleconferences and webinars is on the rise, but we also get input from direct visits to the field. We also get priorities from Congress, in addition to financial resources.

### How do we introduce new technologies to the widest audience in the shortest time?

Innovation can provide game-changing technologies, but only if our regulators are prepared to respond to questions about their use and safety. Perhaps university seminars would be a good way to spread information more quickly and efficiently. External peer review is another way. The use of 501(c)(3) organizations and the USDA's Foundation for Food & Agricultural Research (FFAR) are other mechanisms that might be helpful for emerging technologies and increasing public acceptance of them. The need for sharing information will certainly help, but management of IP and costs remain an issue.

## Group Breakout Sessions

Following the Day One plenary session, workshop participants separated into mixed sector (e.g. agency, industry, university) breakout groups to discuss the key topic areas introduced by the speakers, as well as ideas generated during the panel discussions. Topics discussed during the facilitated breakout sessions were prioritized and summarized to provide direct feedback to all workshop participants.

Breakout team members provided their perspective as to how to best achieve the following general expected outcomes from the workshop.

Over two-days of breakout sessions, the teams reviewed the most important issues involving the development, regulation and acceptance of new agricultural technologies. After prioritizing the issues, each team outlined the opportunities, challenges and next steps that need to be addressed to develop a framework for consideration by a future steering group (as yet unnamed).

The following is an aggregated composite summary of the major conclusions and recommendations from all of the breakout teams. This summary is organized around several common themes that were identified during the sessions to help frame the actions for future follow up by a steering committee.

**Key Goals**

- Improve understanding and acceptance of agricultural innovations
- Meet needs of the regulatory agencies to facilitate new technology approval
- Improve education and training in regulatory sciences, studies and workforce
- Create framework to support changes in technology regulation and acceptance

### Technology in the agricultural industry is entering a period major change, bringing new opportunities to farmers and new challenges to regulatory authorities

Innovations in crop protection chemicals, biologicals, biotechnologies and farming practices have helped farmers increase yields, optimize ROI and enhance agricultural sustainability. While the benefits of innovation are obvious to those involved in agriculture, there is a disconnect with the general public, which fears the industry is minimizing potential risks to human health and the environment. To meet the rising food demand of a growing world population, the development of new technologies is essential, but this is likely to create additional public concerns.

## Transparency is critical to establish public trust and credibility as innovative products are introduced into the marketplace

Failure to adequately address potential public concerns regarding agricultural innovations creates a climate of distrust and contributes to a lack of credibility within the industry. Calls for greater transparency in testing and regulatory oversight may in some cases conflict with legitimate industry concerns about protecting intellectual property rights. Regulatory agencies are called upon to reassure the public that today's technologies will not come at the expense of human health or the environment, and must balance the application of scientific risk assessment with demands for stricter regulation.

## Effective education and communication are essential to improve innovation acceptance

As the science and complexity of risk assessment continues to evolve, additional demands for testing and oversight will likely cause increased registration delays and widen the gap between the industry and the public regarding the safety of agricultural technologies. Effective communication from credible voices in consumer-friendly media regarding the benefits and safety of innovation is needed to restore trust and improve acceptance. New regulatory science curriculums at land-grant universities (e.g. NCSU) are needed to train the next generation of regulators and agricultural agency workforce.

## Multidiscipline collaborations are the key to support our regulatory process and help engender public trust

The process of registering, commercializing and stewarding new technologies could benefit from further optimization to ensure the needs of farmers and the concerns of the public are properly balanced. Multidiscipline teams representing diverse interests can bring different competencies and perspectives to the registration and acceptance of new technologies. Examples of multidisciplinary teams coming together to credibly address a critical issue include the President's National Pollinator Strategy and the Delta Council's "Locker Room" approach to farm-raised catfish.

For further breakout details, see Consolidated Breakout Session Summary Table – Appendix C

## STEERING COMMITTEE

To bring the workshop ideas together in a manageable plan, the formation of a governing Steering Committee (SC) is needed. While the purpose of this conference was not to select a SC, several workshop participants (Laura McConnell (Bayer), Sally Schneider (USDA-ARS) and Bill Kuckuck (CLA)) volunteered to help move this process forward. This team will review potential nominees from the stakeholder list with the hope of having a fully functioning Steering Committee in place by years' end.

Next Steps

- Select a Steering Committee
- Non-biased, representative, credible and global-thinking
- Initial SC taken from Workshop participants, outside additions later
- Establish clear goals and objectives, including action milestones
- Develop a funding framework (short-term and long-term)
- Consider matching funds, foundation support (university examples)
- Conduct survey of similar existing programs (to avoid duplication of costs/effort)
- Consider a Pilot Project ("Model Farm")/systems approach (e.g. USDA-ARS LTAR)
- Refine Goals & Objectives by and implement plan in first quarter of 2017

## Final Workshop Comments by Organization

Before concluding the workshop, each participating organization was asked to provide final thoughts about the conference, which is summarized in the table below. Several participants remarked that a quote from Pat Harris (NCDOA) succinctly summarized the direction going forward:

"To develop a long-term strategic plan to use regulatory sciences to affect positive change for social acceptance of new technologies in agriculture"

| Organization | Comment |
|---|---|
| USDA | Build broader collaboration with other groups. Committed to remain part of this process. More of USDA's organization should be included in this. |
| NC DOA | Encouraged by discussion and commitment to improve communication and collaboration. Recognize "higher calling" to improve agriculture's future. |
| NASDA | State departments of agriculture are looking for sound ag policies. We need to balance innovation and regulatory burden. |
| BASF | Establishing greater credibility and trust are needed because sound science and risk assessment alone are not enough. |
| NCSU | We are all in – this fits our desire for collaborative research/regulatory education and we want to take the lead as a land-grant university. |
| Delta Council | We share the same concerns and want to continue our participation. With so many farm organizations there is a need to consolidate representation. |
| NC Biotech Center | Assumed that regulatory process was straight-forward/efficient, but learned otherwise. We must guard against "non-scientific" communication of science. |
| Consultant | EPA understands the science, but must find ways to better communicate it to the public. The role of land-grant universities can be of great importance. |
| CLA | There is a need to focus on next steps. Because of normal distractions, the use of a virtual Dropbox tool would be helpful to share information and dialogue. |
| Bayer | Enjoyed the team dynamics and ideas on collaboration & sharing new insights and perspectives. Advancing ideas on innovation requires solid deliverables. |

## APPENDIX A – LIST OF PARTICIPANTS

Organizers: Iain Kelly (Iain.kelly@bayer.com), Alan Ayers (alan.ayers@bayer.com), and Laura McConnell (laura.mcconnell@bayer.com)

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## APPENDIX B – WORKSHOP AGENDA

Thursday, July 28

8:00 AM Welcome presentations from Bayer and NCSU

Workshop Introduction, Larry Roberts, moderator

Presentations from Representative Organizations

| | |
|---|---|
| 8:40 am | Iain Kelly, Bayer |
| 9:00 am | Sally Schneider, USDA-ARS |
| 9:20 am | Steve Lommel, NCSU, College of Life Sciences |
| 9:40 am | Chip Morgan, Delta Council |
| 10:00 am | Rick Keigwin, US EPA, Office of Pesticide Programs |
| 10:20 am | Break |
| 10:40 am | Moderated Panel Discussion |
| 11:40 am | Morning Wrap-up and Charge to Breakout Groups |
| 12:00 pm | Lunch |
| 12:30 pm | Breakout Session |

3:00 pm Reports from Breakout Groups and Wrap up

Group travel to Bayer campus and tour of the North American Bee Care Center

Friday, July 29

8:00 am Review of Day 1 themes and charge to breakout groups

8:30 am Breakout Groups Continue to Refine Ideas

| | |
|---|---|
| 11:00 am | Final Session: Development of a Path Forward and Identify Actions |
| 12:00 am | Lunch |

Group tour of NCSU Lake Wheeler Field Laboratory

Adjourn

Moderator/Facilitators/Recorder

Larry Roberts, Consultant, Roberts Business Group, Larry@robertsbg.com

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# APPENDIX C – BREAKOUT TEAM SUMMARY TABLE

## TECHNOLOGY AND STAKEHOLDER INVENTORY

| Technology | Stakeholders (representative sample) |
|---|---|
| Products | Regulatory Agencies |
| Biotechnology | EPA, USDA – APHIS, FDA |
| Biologicals | Research Organizations - Universities |
| Synthetic chemicals | ARS , NIFA, CAST, CRADA,UL lab, IR-4 |
| Farm Practices | Conservation Organizations |
| Water/Conservation practices | NRCS, Fish & Wildlife |
| Best Management Practices | State environmental quality groups |
| Stewardship | State Departments of Agriculture |
| IPM/IWM | Basic Manufacturers (seeds/crop protection) |
| Big Data/Digital Ag | NGOs - NRDC, EDF, EWG, Sierra, Nature Consv. |
| Precision Ag /Robotics/Drones | Trade Assoc. – CLA, ASTA, USFRA |
| Risk Management/Education | Producers – Farm Bureau, NCC, NCG, ASA, FTM |

## COMMUNICATIONS

| Opportunities | Challenges |
|---|---|
| Leadership (Voices) | Regain trust |
| National voice (Icon, Bell Cow) | Consumer science literacy |
| State voice (Aggie Network, Barnyard) | Scalability of outreach |
| Transparency – truth validator/self-police | Politicization of science |
| Rapid response team | Agency need of skillset |
| Messages/Activities | Not predictable |
| Build benefits messages | Corporate data mistrust |
| Consumer values/Media Channels | NGO claims not validated |
| Scalability | NGOs using courts |
| Curriculum – Regulatory Science | Unknown risk assessment w/new technologies (we don't know what we don't know) |
| Food Game for younger audiences | |
| Local voices recruitment | Global regulatory process/impact |
| Strength of regulatory standards | Funding/Other resources |

## NEXT STEPS

Appoint Steering Committee (nominate by Sept 15, Appoint by Oct 1, Meet 4th Q 2016)

Conduct survey of existing programs (avoid duplication of effort)

Create Pilot Project (e.g. "Model Farm") & build systems approach (e.g. USDA-ARS LTAR project)

Refine Goals & Objectives by and implement plan by 1st Q 2017